

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	
	)	MDL NO. 1203
	)	
THIS DOCUMENT RELATES TO:	)	
	)	
SHEILA BROWN, et al.	)	
	)	CIVIL ACTION NO. 99-20593
v.	)	
	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203
	)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8999

Bartle, J.

January 31, 2013

Bethany K. Diggs ("Ms. Diggs" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bassem Mikhail, M.D. Based on an echocardiogram dated May 10, 2002, Dr. Mikhail attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.<sup>3</sup> Based on such findings, claimant would be

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2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Mikhail also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

entitled to Matrix A-1, Level II benefits in the amount of \$538,973.<sup>4</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Muhammad Yasin, M.D., stated that Ms. Diggs had "[m]ild to moderate mitral" regurgitation. Dr. Yasin did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Yasin further opined that claimant's "[l]eft atrium is dilated," which he measured at 4.2 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b).

In August, 2005, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for Dr. Mikhail's

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors needed to qualify for a Level II claim.

finding that claimant had moderate mitral regurgitation because the "[r]eal time images show minimal to mild at most mitral regurgitation." Dr. Gradus-Pizlo also concluded that there was no reasonable medical basis for Dr. Mikhail's finding that claimant had an abnormal left atrial dimension because claimant's "left atrial size is normal."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim of Ms. Diggs. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>5</sup> In contest, claimant argued that the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that Dr. Mikhail's conclusions were reasonable because they were consistent with the findings of Dr. Yasin, who performed claimant's echocardiogram under the Trust's Screening Program.<sup>6</sup>

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

6. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement). In contest, claimant also submitted a copy of her Gray Form. Under the Settlement Agreement, the Gray Form is used to report on the results from the Screening Program. See Settlement Agreement §§ VI.C.2.f., IV.C.4.a.(8). In the Gray Form, Dr. Yasin attested that claimant had moderate mitral regurgitation.



According to claimant, a finding of "mild to moderate" mitral regurgitation "can translate into 'moderate' mitral regurgitation for purposes of the Settlement Agreement."<sup>7</sup> Claimant further contended that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."<sup>8</sup> Finally, claimant suggested that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement and that the auditing cardiologist simply substituted her own opinion for that of the attesting physician.<sup>9</sup>

The Trust then issued a final post-audit determination again denying the claim of Ms. Diggs. Claimant disputed this final determination and requested that the claim proceed to the

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7. In support of this assertion, claimant relied on an echocardiogram report for another claimant in which, in addition to stating that the individual had "mild to moderate" mitral regurgitation, the cardiologist specified a RJA/LAA ratio of 25%, which constitutes moderate regurgitation under the Settlement Agreement. See Settlement Agreement § I.22. The echocardiogram report for the claim of Ms. Diggs, however, did not specify a percentage as to mitral regurgitation. In any event, the issue here is whether Ms. Diggs has established a reasonable medical basis for her claim.

8. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed the echocardiogram of Ms. Diggs.

9. Claimant also asserted that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant also referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how those filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On March 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6077 (Mar. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006, and claimant submitted a sur-reply on June 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>10</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Diggs reasserts the arguments that she made in contest. In addition, claimant suggests that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation. According to claimant, "[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'"<sup>11</sup>

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11. In her show cause submission, Ms. Diggs also challenges the auditing cardiologist's conclusion that there was no reasonable medical basis for finding that she had an abnormal left atrial

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In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because she did not rebut any of Dr. Gradus-Pizlo's specific findings.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because the claimant's echocardiogram demonstrated only mild mitral regurgitation.

Dr. Vigilante explained:

Visually, mild mitral regurgitation was suggested with a laterally directed jet into the left atrium on the apical four chamber view. Only trace mitral regurgitation was suggested in the apical two chamber view and parasternal long-axis view. I digitized the cardiac cycles in the apical four chamber view in which the mitral regurgitant jet appeared the most significant. I digitally traced and calculated the RJA and LAA. I was able to accurately planimeter the RJA in the mid portion of systole. In the apical four chamber view, the largest representative RJA was 1.9 cm<sup>2</sup>. The LAA in the apical four chamber view was 17.0 cm<sup>2</sup>. Therefore, the largest representative RJA/LAA ratio was 11% in the apical four chamber view. This ratio never came close to approaching 20%. The mitral regurgitant jet was within 1 cm of the mitral annulus in the apical two chamber view. Therefore, trace mitral regurgitation was suggested in the apical two chamber view.

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11. (...continued)  
dimension. Given our resolution as to the issue of claimant's level of mitral regurgitation, we need not address whether claimant has established the requisite complicating factor needed to qualify for Level II benefits.



The LAA in the apical two chamber view could not be accurately determined as the superior aspect of the left atrium was not visualized. There were no sonographer-determined RJA or LAA measurements on this tape.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest Dr. Gradus-Pizlo's and Dr. Vigilante's determinations that claimant's echocardiogram demonstrated at most mild mitral regurgitation. In particular, Dr. Gradus-Pizlo concluded that the echocardiogram "show[ed] minimal to mild mitral regurgitation."<sup>12</sup> Dr. Vigilante determined that the largest RJA/LAA ratio was 11% and did not come close to approaching 20%. Claimant never identified any specific errors in Dr. Gradus-Pizlo's or Dr. Vigilante's conclusions.<sup>13</sup> Mere disagreement with the auditing cardiologist and Technical Advisor without identifying and substantiating any specific errors by them is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of

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12. For this reason as well, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Gradus-Pizlo merely substituted her opinion for that of the attesting physician. Instead, Dr. Gradus-Pizlo specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Neither claimant nor claimant's attesting physician, however, adequately refuted or responded to this determination.

13. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Gradus-Pizlo determined in audit, and Ms. Diggs does not adequately dispute, that the attesting physician's finding of moderate mitral regurgitation was unreasonable because the "[r]eal time images show minimal to mild ... mitral regurgitation." Contrary to claimant's argument, Dr. Gradus-Pizlo properly applied the reasonable medical basis standard established under the Settlement Agreement.

Moreover, we find that Dr. Mikhail's conclusion as to claimant's level of mitral regurgitation is not supported by the echocardiogram report on which he relied, as the report simply states that claimant had "[m]ild to moderate mitral" regurgitation. Under these circumstances, the attesting physician's conclusion lacks a reasonable medical basis. Dr. Mikhail provides no explanation for his conclusion or for the discrepancy between his finding and the conclusion reflected on the echocardiogram report. We have previously held that a claimant cannot establish a reasonable medical basis for a finding of moderate mitral regurgitation where "the report for

the echocardiogram underlying the Green Form does not state definitively that claimant had moderate mitral regurgitation," and where "the other echocardiogram reports<sup>14</sup> submitted by claimant do not indicate that [claimant] was diagnosed with moderate mitral regurgitation." See PTO No. 5229 at 8 (May 18, 2005) (emphasis in original). The court cannot allow a claimant to prevail on his or her claim simply because an echocardiogram report references the word "moderate," particularly where that conclusion has been found to be unreasonable after audit.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of the claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. Claimant's reliance on the echocardiogram obtained as a result of the Screening Program is misplaced. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of

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14. Claimant's Show Cause Record also includes a report for an echocardiogram performed on August 23, 1999. In the report, Asim J. Chohan, M.D., stated: "[m]itral valve regurgitation, mild."

the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Diggs for Matrix Benefits.